

# SATILLA RIVER EXPERIMENT STATION

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20 January 1998

FDA's Docket Management Branch (HFA-305) 98 JAN 27 P3:38  
12420 Parklawn Drive  
Room 1-23  
Rockville, MD 20857

Re: New Drug Registration for Minor Species  
(Docket No. 97N-0117)

Dear Sir:

We are a new commercial catfish venture, and as such are interested in forestalling future fish health problems by increasing our treatment options.

The issues are best addressed as follows;

A. We agree with a temporary relief using proposed extralabel provisions. The increase or decrease in use of such chemicals will provide the producer with an incentive or otherwise for further approval. All potential products (i.e. hormones) should be included at this stage as we feel that the public issue at this stage is minor.

B. All existing disincentives should be removed to promote market development.

C. Any additional funding would be welcomed in this rapidly growing ( esp. catfish) industry where foreign imports could be reduced. We suggest establishing an internet database for such information.

D. We feel that any exclusivity would discourage competition, especially in a minor use product. The whole issue of exclusivity depends on the range of products available. An exclusivity option could be considered if only a single product is available.

E. There should be no requiring of data sharing as we feel that competition should be stimulated. A limited liability clause could cover any data sharing requirement.

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F. A "minor use animal drug" statutory designation would be very useful. Some incentives could be considered at this stage.

G. We are unaware of proposed constraints but would assume that consumer protection is not a priority with a non-food animal.

H. This is not our issue as catfish producers, but would hope that federal funding would be available for expert review panels.

I. We need as much private input as possible especially from foreign sources where some of the leg-work for products approval could have already been done.

We thank you for interest in this regard and hope that we have made a contribution.

Respectfully,

A handwritten signature in dark ink, appearing to read "M North".

Michael S. North for  
James S. Bardsley, Jr.

JSBJr./lt

cc: Gary J. Burtle

96 Satella Drive  
White Oak, Ga 31568

